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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

WILSON, LARRY ROSS

ART UNIT

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3767

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/587,534	Applicant(s) BOOTH, NORMAN	
	Examiner LARRY R. WILSON	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 July 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>26 Jul 2006, 18 Apr 2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-7 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,643,281 to Paul V. Suhocki et al. (Suhocki) in view of U.S. Patent 5,556,380 to Mark T. Ridinger et al. (Ridinger).

In regards to claim 1, Suhocki teaches a catheter assembly which includes at least one introducer (Fig. 1, VC), the at least one introducer defining at least one passage (col. 3, lines 10-11 – venous catheter VC inherently has a passage therethrough), an elongate tubular member (Fig. 1, #12) slidably received within the at least one passage of the at least one introducer (Fig. 1), the tubular member having a proximal end and a distal end and at least one lumen extending between the proximal end and the distal end (col. 3, lines 16-17 – tubular member inherently has at least one lumen and a distal and proximal ends), and an elongate, shape-imparting element (Fig. 1, #18a, 18b) received in the at least one lumen of the tubular member (Fig. 1), the shape-imparting element imparting a predetermined shape to the distal end of the tubular member when the distal end of the tubular member is extended beyond a distal end of the introducer (col. 3, lines 38-40), a distal end of the shape-imparting element extending from the at least one lumen of the

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tubular member (Fig. 1), but does not teach and being anchored proximally a distal end of the introducer.

Ridinger teaches being anchored proximally a distal end of the introducer (Fig. 1, #16b).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the anchor of Ridinger in the fibrin remover of Suhocki in order to provide a snare wire with a 360° wrap to more effectively remove fibrin sheaths forming on a vascular catheter as explicitly taught by Ridinger.

In regards to claims 2-7, Suhocki, as modified by Ridinger, further teach a proximal end of the shape-imparting element is connectable to a control mechanism which, in use, applies torsion to the shape-imparting element (Ridinger col. 3, line 49-col. 4, line 2); in which the predetermined shape imparted to the distal end of the tubular member is a loop formation (Suhocki Fig. 1, #14); in which the tubular member forms a cranked arm (Suhocki Fig. 1, #22, 24) when it is extended from its introducer, the cranked arm being arranged transversely with respect to a longitudinal axis of the introducer (Suhocki col. 3, lines 39-42) and the cranked arm leading into a spiral shape forming the loop formation (Ridinger col. 3, lines 57-58 – it would have been obvious to one of ordinary skill in that the loop when torqued as taught by Ridinger would inherently take on a helical shape due to fictional interaction between the venous catheter and the snare wire); in which the spiral shape circumscribes at least 360° (Ridinger col. 3, lines 30-33); in which the spiral shape circumscribes about 540° (Ridinger Fig. 2C & col. 3, line 54-col. 4, line 2 – the snare wire has formed a spiral of several twists around

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the central wire 14); in which the cranked arm extends from the end of the introducer at an included angle of about, or exceeding, 90° (Suhocki col. 3, lines 39-42).

In regards to claim 16, Suhocki teaches a catheter assembly which includes at least one introducer (Fig. 1, VC), the at least one introducer defining a passage (col. 3, lines 10-11 – venous catheter VC inherently has a passage therethrough), an elongate, tubular member (Fig. 1, #12) slidably received within the passage of the at least one introducer (Fig. 1), the tubular member having a proximal end and a distal end and a lumen extending between the proximal end and the distal end (col. 3, lines 16-17 – tubular member inherently has at least one lumen and a distal and proximal ends), and an elongate, shape-imparting element (Fig. 1, #18a, 18b) received in the lumen of the tubular member (Fig. 1), a cranked arm portion (Fig. 1, #22, 24) extending transversely relative to a longitudinal axis of the introducer (col. 3, lines 39-42) and a loop formation (Fig. 1, #14) supported on the arm portion. But Suhocki does not teach a distal end of the shape-imparting element extending beyond a distal end of the tubular member and being anchored proximally a distal end of the introducer ... so that torsion imparted to a proximal end of the shape-imparting element causes rotation of the arm portion about the longitudinal axis of the introducer.

Ridinger teaches a distal end of the shape-imparting element extending beyond a distal end of the tubular member and being anchored proximally a distal end of the introducer (Fig. 1, #16b), ... so that torsion imparted to a proximal end of the shape-imparting element causes rotation of the arm portion about the longitudinal axis of the introducer (Ridinger col. 3, line 49-col. 4, line 2).

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the anchor of Ridinger in the fibrin remover of Suhocki in order to provide a snare wire with a 360° wrap to more effectively remove fibrin sheaths forming on a vascular catheter.

3. Claims 8-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Suhocki, as modified by Ridinger, as applied to claim 1 above, and further in view of EP 0 749 435 to Mary Elizabeth Bush et al. (Bush).

In regards to claims 8-15, Suhocki, as modified by Ridinger, teaches the assembly of claim 1, but does not teach the assembly includes at least two introducers, each introducer having a tubular member associated with it; a first introducer received within a passage of a second introducer, a second tubular member, being slidably received within a passage of the second introducer; the second tubular member is carried on a shape-imparting element received within a lumen of the second tubular member; the shape-imparting element associated with the second tubular member extends beyond a distal end of the second tubular member; a distal end of the second shape-imparting element is anchored distally with respect to the distal end of the second tubular member but proximally with respect to the distal end of the first introducer; an anchor point of the first shape-imparting element is in register with an anchor point of the second shape-imparting element; both anchor points are arranged on the first introducer; each shape-imparting element is in the form of a shape memory alloy wire.

Bush teaches at least two introducers (Fig. 11, #14h, 62), each introducer having a tubular member associated with it (Fig. 11, #12h, 18h); a first introducer is received within a

passage of a second introducer (Fig. 11, #14h, 62), a second tubular member, associated with the second introducer, being slidably received within a passage of the second introducer (Fig. 11, #12h); in which the second tubular member is carried on a shape-imparting element (Fig. 11, #18h – col. 7, lines 13-15) received within a lumen of the second tubular member so that the second tubular member is able to be formed into a second predetermined shape when the second tubular member is extended from the second introducer (col. 11, lines 42-45); the shape-imparting element associated with the second tubular member extends beyond a distal end of the second tubular member (col. 11, lines 42-45); a distal end of the second shape-imparting element is anchored distally with respect to the distal end of the second tubular member but proximally with respect to the distal end of the first introducer (Ridinger Fig. 1, #16b – it is implied that the anchor would be distal of the second tubular member because the first and second tubular members are nested within the second introducer as shown in Bush Fig. 11); an anchor point of the first shape-imparting element is in register with an anchor point of the second shape-imparting element (Fig. 1, #26 – both loops are in register with one another at point 26 where the upper set splits from the lower set); both anchor points are arranged on the first introducer (Ridinger Fig. 1, #16b – it is implied by the disclosure of Ridinger that attaching to the first introducer would allow 360° wrapping to form a more effective loop); each shape-imparting element is in the form of a shape memory alloy wire (col. 7, lines 34-37).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have included the multiple introducers of Bush in the fibrin removers of

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Suhocki in order to provide greater redundancy should a wire fail as explicitly taught by Bush.

Conclusion

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LARRY R. WILSON whose telephone number is (571)270-5899.

The examiner can normally be reached on Monday-Thursday 7:00 AM - 5:30 PM (EST).

5. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin C. Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

6. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/L. R. W./

Examiner, Art Unit 3767

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761